DEVELOPMENT AND INVESTIGATION OF SYNTHETIC SKIN SIMULANT PLATFORM (3SP) IN FRICTION BLISTER APPLICATIONS

A Thesis

by

CARLOS ANDREW GUERRA

Submitted to the Office of Graduate Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

December 2010

Major Subject: Mechanical Engineering

Development and Investigation of Synthetic Skin Simulant Platform (3SP) in Friction Blister Applications

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Approved by:

Chair of Committee,	Christian Schwartz
Committee Members,	Melissa Grunlan
	Hong Liang
Head of Department,	Dennis O'Neal

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ABSTRACT

Development and Investigation of Synthetic Skin Simulant Platform (3SP) in Friction Blister Applications. (December 2010)

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Chair of Advisory Committee: Dr. Christian J. Schwartz

Skin is the largest organ of the human body. It is the first line of defense between the vulnerable organs and tissues of the body and the environment. Healthy skin is paramount to avoiding infection and disease. Therefore, any breach in the skin represents a significant risk to the health and comfort of its owner. Friction blisters are one of the most common modes of damage to human skin. In some extreme cases, such as those who suffer from Epidermal Bullosa, friction blisters are a very common and painful occurrence.

Prior research on blister formation has been performed at mostly an observational level. In some cases, blisters have been deliberately created on human volunteers or animal test subjects. However, these studies are very difficult to recreate due to the legal issues of human and animal testing and the fact that no two people will have the same response to external stimulus. Other studies have followed athletes or soldiers who use different textile fabrics for socks or clothing to determine which have significant effects.

Concurrent studies have focused on mimicking human skin for haptics research in product development. These have made great strides in introducing engineering

properties such as coefficient of friction (COF) and elastic modulus into the field of skin study. While these studies are very useful to understanding the properties and mechanisms of human skin in rubbing applications, their primary audience is the cosmetics industry or product developers.

There is a significant opportunity to take a similar approach of applying an engineering viewpoint to repeatably model the onset and formation of blisters on human skin. The authors have developed the Synthetic Skin Simulant Platform (3SP) to fulfill this role. The 3SP is a three-layer composite of elastomeric materials that outputs a visually recognizable blister upon sufficiently strong shear loading.

The authors determined through two factorial experiments conducted on a custom wear testing table which variables were most significant to blister formation in the 3SP. The results showed that COF and dermal stiffness are the primary contributors. This agrees with prior literature about the significance of COF, and it suggests that dermal stiffness is a significant factor that merits examination in future blister research.

Finally, the authors ran another experiment to ascertain the influence of textile fabrics and surface treatments on blister formation in the 3SP. The results demonstrated that surface treatments of corn starch and aloe-based lubricant were effective at mitigating blister formation on the 3SP. Furthermore, the results show that fabric is also bordering statistical significance on blistering.

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I would like to thank my committee chair, Dr. Schwartz, and my committee members, Dr. Grunlan and Dr. Liang, for their support throughout the course of this research. I would also like to thank Dr. Hartwig for acting as a substitute member for my defense.

Thanks also to my colleagues for making my time at Texas A&M University an enjoyable and mentally stimulating environment in which to work. Thanks to Kevin Plumlee for his assistance and helpful knowledge base in facilitating several of the mechanisms of my research. Thanks to the staff and faculty for providing excellent service and education.

Finally, thanks to my mother and father for their ever-present support in all of my endeavors. I am blessed by their sacrifices to provide a means to my pursuit of happiness. Thanks to my wife, Kristen, for all her love and patience as I completed my work.

NOMENCLATURE

COF	Coefficient of Friction
SC	Stratum Corneum
3SP	Synthetic Skin Simulant Platform
SEM	Scanning Electron Microscope

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CHAPTER I

INTRODUCTION

Human skin is the largest organ in the human body, the primary line of defense between internal organs and the outside world. Therefore, any disease or trauma that causes a breach in this protective layer threatens not just the comfort, but the life and health of its owner. Blisters are a very common mode of skin damage, with consequences ranging from mild discomfort to infection and disease. Blisters may be caused by heat, chemical reaction, or even skin disorders; however, the focus of this research is friction blistering.

Skin is composed of multiple layers, beginning with the dermis, set upon a subcutaneous layer of fat. Progressively dying cells rise from the dermis to form the epidermis, which may be divided further into the stratums basale, spinosum, granulosum, lucidum, and corneum. Friction blisters form under shearing trauma when cells in the stratum spinosum undergo necrosis, allowing the stratum granulosum to separate from the stratum basale[1, 2]. The newly-formed pocket between these two stratum then fills with body fluid, producing a bubble blister or an outright tear in the skin. The type of blister formed – bubble or tear – is contingent on body location and the shearing forces involved.

Frictional and elastic properties of skin vary significantly in relation to age, sex, anatomical regions of the body, and hydration[3-5]. The stratum corneum (SC) accounts for the frictional characteristics of skin. Although it is only 10-20 μm on average, the SC

This thesis follows the style of Wear.

provides a 70% reduction in frictional forces in tape stripping experiments[6]. Skin coefficient of friction (COF) is one of the critical properties to comprehend for friction blistering. Blisters are not the result of superficial damage from rubbing, but rather the transmission on transverse loading to the stratum spinosum. Therefore, skin with a high COF will transmit a high percentage of a given shear load to the spinosum. The elastic property of skin is highly complex due to its multiple layers and anisotropic behavior in addition to the aforementioned factors of age, sex, and region. *In vivo* experimentation has demonstrated that skin behaves much like an elastomer in tensile applications. Upon initial loading, there is little resistance to strain, but, after a critical strain point, the skin requires significantly more load to stretch any further[7].

Modeling skin, then, is a very complicated task. In doing so, it is important that the model reflect its application. In the case of skin grafts, the key is biocompatibility. For cosmetics, it is COF. There is no prior research regarding a skin model for friction blistering tests. The authors developed a construct called the Synthetic Skin Simulant Platform (3SP) to model friction blistering on human skin. This thesis outlines the authors' process in creating this model and investigating its behavior for future studies. In Chapter II of this work, the authors first study examined which factors had significant influence on blister formation on the 3SP. The factors that were tested were inferred from prior literature on the subject of friction blistering.

The second component of the research was to examine how the 3SP would perform under the influence of surface treatments and contact with different textile fabrics. Both these variables are of interest in medical and research fields in the interest of blister prevention[8, 9]. The process and results are described in Chapter III.

CHAPTER II

DEVELOPMENT OF A SYNTHETIC SKIN SIMULANT PLATFORM FOR THE INVESTIGATION OF DERMAL BLISTERING MECHANICS

Introduction

Friction blisters are a very common mode of skin damage, with consequences ranging from mild discomfort to infection and disease. Skin is composed of multiple layers, the innermost layer being the dermis which sits upon a subcutaneous layer of adipose tissue. The outermost layer of skin, the epidermis, is composed of progressively dying and hardening cells that migrate away from the dermis before sloughing away. Epidermal layers, in the order of their distance from the dermis, include the stratums basale (newly generated cells), spinosum, granulosum, lucidum, and, finally, the corneum at the very outside surface of the epidermis. The stratum spinosum acts as the anchoring system for layers in the epidermis; therefore, when these cells are injured, they allow the formation of pockets of fluid to form between strata in the epidermis [10]. This is distinct from surface damage. When the coefficient of friction between a foreign surface and the corneum layer is sufficient, slippage ceases and shear load is transferred to the layer interfaces within the epidermis [2]. Friction blisters form under such shearing trauma when the stratum granulosum separates from the stratum basale [1]. The newly-formed pocket between these two strata then fills with fluid, leading to an inflamed bubble which becomes susceptible to further injury. Occupational blister research has been pursued for several decades, dating back to the 1950's with Naylor et al. and Sulzberger et al. performing in situ blistering tests on human test subjects [2, 11]. Subsequent blister research has focused on observation of blister formation influenced by coefficient of friction (COF) [10] and moisture effects [9] at the skin site. Research into the mechanical [3, 12] and tribological properties [13] of skin has accelerated due to the interests of tactile optimization of products, as well as the cosmetics industry.

In examining prior research of friction blisters the authors noted that, while impressively systematic, these studies tended to take an observational or biological approach to understanding blister formation. There has been little attempt to characterize blistering from an engineering perspective. Furthermore, all investigators that have worked in this field have been limited by the necessity to conduct experiments on human test subjects. Notwithstanding the ethical and legal difficulties of intentional skin injury of test subjects, there are also very significant issues of repeatability with human test subjects. Studies have shown that the behavior of human skin is highly variable from person to person [7]. As such, there is a significant need for the creation of a construct that can accurately model the behavior of human skin under shear loading. An investigation of the mechanics of skin blistering has revealed five parameters of interest that were the subject of this investigation: coefficient of friction, dermal stiffness, interlayer bond strength, normal load, and shear rate. By focusing on these central mechanical and tribological parameters of skin, the authors sought to design a synthetic surrogate system to serve as a research platform for continuing blister research.

Material and Methods

Platform Design and Preparation

The design of the Synthetic Skin Simulant Platform (3SP) focused on the blistering mechanism of human skin. Blisters form between layers in the epidermis when subjected to shear loading, thus attention was paid to proper selection of materials in light of the reported mechanical properties of real skin. The 3SP implemented a tri-layer design to simulate blister formation under applied shear loading. The structure of the 3SP is shown in Figure 1.

The top layer of the 3SP is referred to as the Epidermal Simulant Layer (ESL). It consisted of 80-mm thick transparent silicone rubber, to simulate the stratum corneum. As with human skin, the critical property of this layer is its coefficient of friction (COF). Silicone was chosen because it has been shown to approximate the COF of human skin against a number of surfaces [12]. The transparency of the ESL was also deemed important in order for blister area to be measured after testing, as described below. For each platform constructed, the silicone was cut into a 5 x 7.6-cm rectangle to prepare for bonding to the layer below. The Dermal Simulant Layer (DSL) consisted of a 318-mm thick layer of either polyurethane elastomer (McMaster-Carr) or neoprene rubber cut to a 7.6-cm square. The choice of DSL material allowed for investigation of the effects of dermal stiffness on blister formation. When selecting materials for this layer, the key consideration was its response to normal loading; the authors selected the above two materials to simulate the range of stiffness found at different anatomical sites on the body. Due to the thinness and compliance of the top two layers, the authors found that the ESL and DSL experienced significant substrate effects when they were adhered directly to the mounting substrate, thus the Subdermal Simulant Layer (SSL) was incorporated. The SSL consisted of 318-mm thick latex rubber (McMaster) cut to a 7.6-cm square. Another objective of incorporating the SSL into the platform was to simulate the tendons, fat and muscles that sit between bone and the dermis in the body.

In addition to the properties of the 3SP layers, another critical parameter of the construct was the adhesive strength between the ESL and DSL, since it was the interface involved in blistering. A methyl ethyl ketone adhesive (Loctite® No. 79051333) was selected as an adhesive because it provided good adhesion between the two layers and the adhesive strength could be modulated by dilution with acetone. The ESL and DSL were bonded using the adhesive in regular or thinned (50% acetone dilution, by weight) form, to provide 'high' and 'low' values of adhesion for the factorial experiments described below. The adhesive was applied evenly to the surface of the ESL using a paint brush. Any bubbles between the ESL and DSL were manually smoothed out by hand, paying special attention to minimizing the deformation of the layers during application. A flat plate was pressed against the top of the ESL immediately after establishing contact with the DSL to produced smooth bonding across the interface. A distributed compressive load of approximately 55 N was applied for 30 minutes during adhesive curing. A silicone-based adhesive was used to join the DSL to the Subdermal Simulant Layer (SSL), as well as the SSL to the mounting substrate. This latter adhesive had much higher bond strength than the ESL-DSL interface to ensure blistering would occur at the appropriate interface. Adhesive was applied to the top of the SSL layer and the ESL-DSL construct was placed upon it. Adhesive was then applied to the mounting substrate (paper-backed acrylic plate) and the entire stacked platform was cured for 12 hours using a distributed compressive force of approximately 30 N.

Prior to experimentation, the authors conducted several preliminary tests to optimize the materials and adhesives used in 3SP samples. Since the 3SP goal represented an unexplored field, it was important to find some functional basis from which to begin tests. Prior skin-simulant studies in haptics and cosmetics were helpful to frame the material perspective. To begin finding the best combination of materials and adhesives, the authors selected 10 different elastomer materials based on their durometer stiffness ratings and four different adhesives based upon availability and suggested use. The stiffnesses were qualitatively rated from 'ultra soft' to 'firm' (McMaster), and loosely guided by the work of Derler et al[12].

The most obvious configuration change between the first generation 3SP samples and the current version was the SSL used. A 12.7 mm thick silicone foam was the first material used in this application. It was abandoned in favor of 3.18 mm thick latex rubber due to its deformation under normal loading being higher than was desired. Additionally, handling and cutting the foam was clumsier than with latex. The silicone foam may be useful for modeling structural soft spots on the human body such as the abdomen; however, this region is not typically associated with blistering. Due to the initial decision to use materials with similar stiffness ratings, the evolution of the DSL material was not an area of emphasis during the early stages of development. It was only after experimentation that the effect of the DSL materials was understood. Two ESL materials were tested: a very thin (0.127 mm) silicone film and a thicker (0.8 mm) silicone rubber. The thicker rubber was selected because the thin film was easily torn apart by the testing apparatus.

A primary focal point of the early development of the 3SP was to find which adhesives were useful to the testing procedure. The goal in selecting the best adhesive was to find one that was strong but easily diluted by a solvent. Four different adhesives were tested at the critical interface between the ESL and the DSL. After testing each adhesive, two emerged as the best performers for application: an aerosol-delivered vinyl/plastic adhesive and a tube-delivered ketone based adhesive. Blister performance was very close with each, but the tube delivered system proved to be much better suited for controlled and repeatable dilution and deposition. Two adhesives were tested for the DSL-SSL and SSL-substrate interfaces: superglue and a silicone based adhesive. It was found that the superglue did not bond well with the latex SSL; since the silicone adhesive performed adequately, it remained throughout the entire test process.

Testing Procedure

A 2^{5-2} fractional factorial experiment was run initially to determine which of the five material and loading parameters had an effect on blister formation and surface damage. These parameters were: a) coefficient of friction (COF), b) dermal stiffness, c) bond strength, d) normal load, and e) shear speed. The experiments were performed with a custom-built dual-axis tribometer. The instrument facilitated precisely controlled contact between a 9.5-mm diameter stainless steel ball and a 3SP sample under a controlled normal load. The ball was reciprocated linearly across the exposed ESL portion of the 3SP surface with a round-trip travel length of 60 mm per cycle, for 100 cycles. COF of the Epidermal Simulant Layer (ESL) was set to 'low' and 'high' values by the presence or absence, respectively, of a thin layer of corn starch on the exposed ESL surface just prior to testing. This produced measured COF values of the ESL of 0.23 and 0.71, respectively. 'Low' and 'high' normal loads of 3 and 9 N, respectively, were chosen to coincide with prior blister research on human subjects performed by other investigators [2]. Normal load was controlled using a pneumatic actuator with analog regulator, with precise values monitored by a three-channel piezo-electric force transducer (Kistler) that was positioned between the stainless stell ball probe and the actuator piston. The transducer output was recorded using data acquisition hardware and software and COF was measured by calculating the ratio of shear force to normal force. The test settings for the experiment are outlined in Table 1.

Two response variables were identified for the tested 3SP samples: blister area and surface damage. Blister area was determined by using image analysis software (ImageJ) to detect the debonded (blistered) area of a tested 3SP sample. A grayscale threshold technique was implemented in the software to automatically detect the blister boundaries through the transparent silicone ESL layer. Surface damage, being very difficult to objectively measure, was instead characterized on a 1 through 5 ordinal scale. These two measures, blister area and surface damage, allowed the investigators to determine damage both to the substrate and the surface. Each level of the surface damage scale is explained below in Table 2.

Based upon an analysis of the data produced by the fractional factorial experiment, a second experiment with newly-constructed 3SP constructs was conducted with the 3SP samples under a 2^3 full factorial plan, with focus on three of the original parameters that showed potential effects on blistering and surface damage: surface treatment, dermal stiffness, and shear speed. These settings are outlined in Table 3. The other two parameters, normal load and bond strength, were held constant at 6 N and undiluted adhesive strength, respectively. Blister area and surface damage were recorded in the manner described above.

Results and Discussion

Observation of the testing revealed that a similar pattern of events occurred among all the 3SP samples that experienced blistering. During the initial abrasion cycles, the sample showed little damage, although there was often a noticeable surface disturbance along the leading edge of the stainless steel probe. This disturbance appeared to reflect the 'bow wave effect' observed during human in situ tests by Kwiatkowska et al. [14]. When the probe moved along the 3SP, the material compresses ahead of it, causing an elevated wave ahead of the indenter and leaving behind a distended wake. Although not all samples blistered, in the samples that did, the onset of blistering at the ESL-DSL interface occurred following an initial period of bow wave production. The early blister first took on the shape of a sharp oval, with its major axis perpendicular to the rubbing direction, which elongated in the direction parallel to motion as it grew. In the case of several samples, blistering occurred at multiple points along the wear path and coalesced into oblong blisters oriented parallel to the direction of motion.

Examination of tested samples, as illustrated in Figure 2, showed varying extents of blister area and surface damage based on the sample and test conditions. The black areas represent ESL-DSL bonding that has been maintained (non-blistered). The gray regions show where the ESL has lifted from the DSL, representing a blister. Not all tests produced blisters and/or surface damage, but Fig. 2 shows significant damage for each run. Surface damage caused an increase in opacity of the silicone ESL layer, which was helpful in characterizing how damaged the surface had become. Table 4 is provided to indicate the results for the various test configurations of the fractional factorial experiment.

An analysis of variance (ANOVA) of blister areas from the first factorial experiment is reported in Table 5.

The table shows that of the five parameters, dermal stiffness and shear speed have a clear effect on blistering, surface treatment appears marginally involved, while changes in bond strength and normal load within the bounds of the experiment had no measurable effect. A non-parametric analysis of the surface damage medians yielded similar conclusions. Modification of surface treatment led to a change in surface damage median of 1.5, while varying dermal stiffness led to a damage median change of 3. Variation of none of the other factors led to this high of a magnitude of median change, and so were assumed not to have a measurable effect on surface damage. The fractionation of the first experiment led to potential confounding of main effects with some of the possible interactions, so based on the results of the ANOVA, the second experiment was run as a full factorial to further investigate surface treatment, dermal stiffness, and shear speed, as well as any possible interactions among them.

The relative insignificance of normal load and bond strength was unexpected. Prior work by Naylor et al. suggests that blistering depends directly on load and number of cycles [2]. This discrepancy may be due to the loading values tested by the authors. Neither Naylor nor Sulzberger [11] monitored normal load in situ during their testing, but rather recorded applied load in the form of set weights. This suggests that method of normal load application must be further investigated as this work continues.

Analysis of variance of the second experiment allowed for both main effects and interactions to be resolved. ANOVA revealed that dermal stiffness (p-value of <0.001), surface treatment (<0.001), and the stiffness-shear speed interaction (<0.001) did have an effect on blister area. Interestingly, shear speed did not have an effect on blister area in the second experiment (p-value 0.837), contrary to the first experiment. This may indicate potential confounding of shear speed with a multi-factor interaction in the first experiment that was not detected due to the limitation of the fractional factorial design. Specifically, there is a possibility that there was an interaction between shear speed and normal load in the first experiment. The reasoning for this is that the second experiment held normal load constant (6 N) while it was varied between two values in the first experiment (3 and 9 N, respectively). Naylor found no correlation between shear speed and blister formation at similar COF values [2]. These results may suggest the effects of viscoelasticity of the materials such that the 3SP (and actual skin) behaves more rigidly at high shear speeds. Kwiatkowska suggested that the strain energy of the material is more easily lost at high sliding speeds[14], so the effect of shear speed may be confounded by the dermal stiffness. The bow wave was particularly prominent in PUR samples. Further investigation will be required to determine the precise effect of shear speed and under what conditions it affects blistering potential. One other point of comparison of the 3SP concept with the behavior of skin is the fact that COF, directly controlled by the surface treatment, had a profound effect on blister formation. This is in agreement with the work of Derler [12] and others [1, 9]. The ultimate objective in developing the 3SP approach is to duplicate the behavior of human skin under shear loading. The results of this study suggest that, while some improvement remains to be undertaken, the fundamental aspects of the 3SP behavior are relevant to skin.

One very intriguing result of this work that may influence future blister research, is the strong effect of dermal stiffness. Akers noted that blisters form more quickly on wet skin[1], attributing it only to the effect of hydration on friction coefficient. In a separate study, Alonso et al. found that hydration also makes skin softer [15]. The use of the 3SP constructs offers one way to connect these two findings in that the results showed dermal stiffness to be just as significant as COF. Though it is difficult to imagine current medical interventions that could easily increase dermal stiffness, this insight may inspire analogous stiffening methods to prevent blister formation.

Future development of the 3SP concept will necessitate studies on explanted skin, whether animal-derived or cadaveric. Such work will be necessary in order to choose construct layers and bonding agents that replicate dermal tissue to an even greater extent than the current work. The modular nature of the 3SP approach allows for innumerable possibilities in optimizing the platform for varying skin types, anatomical locations, and environmental factors. For example, the combination of a soft polyurethane Dermal Simulant Layer (DSL) with no surface treatment to the Epidermal Simulant Layer (ESL) may model the hydrated skin on the abdomen, while a harder neoprene DSL with a corn starch treatment on the ESL could model the dry skin of the volar forearm. The results of this investigation of the 3SP concept demonstrate significant potential for the system to become a powerful tool in future blister research for medical and commercial applications.

Conclusions

The authors have developed a modular, tri-layer elastomer-based experimental construct called the Synthetic Skin Simulant Platform (3SP), that allows for precise investigation of the parameters involved in frictional skin blistering. The 3SP addresses obstacles in skin tribology research regarding the use of human subjects, inability to control biological variability among subjects, and undesired coupling of various mechanical and tribological properties of skin in human subjects. The following conclusions are based on the results of this investigation:

- Blister area and surface damage of the 3SP is strongly affected by the coefficient of friction (COF) of the epidermal layer. Higher COF lead to larger blisters.

- The stiffness of the dermal simulant layer of the 3SP also had a strong affect on the area of blisters generated during the testing. Stiffer dermal materials tended to have smaller blisters than less-stiff dermal materials.
- Shear speed of the stainless steel sphere on the epidermal layer of the 3SP showed varying results based on the normal load applied. This may suggest that speed, normal load, and dermal stiffness interact during blister formation, a postulate that has been suggested by previous researchers.

CHAPTER III

INVESTIGATION OF THE INFLUENCE OF TEXTILE FABRICS AND SURFACE TREATMENTS ON DERMAL BLISTERING

Introduction

Human skin is the body's first line of defense against the environment and the contact point for textile fabrics that everyone experiences on a daily basis. Damage to skin threatens the comfort and health of its user, and it occurs often at a textile-skin interaction. There are several modes of skin damage, but one of the most common is friction blistering. Therefore, mitigating the formation and severity of blistering is a significant endeavor that can improve the quality of life of athletes, soldiers, and even those suffering from skin disorders such as epidermolysis bullosa (EB).

The pathophysiology of blister formation occurs when strata in the epidermis undergo shear loading. When these layers separate, the resulting pocket fills with bodily fluid. Knapik et. al.[10] describes the process in depth in his observational investigation of blister formation and treatment. Several studies have demonstrated coefficient of friction (COF) as one of the primary factors to influence blister formation on human skin, most influentially the works of Sulzberger and Naylor[2, 11]. This is due to higher load transmission to the lower strata of the epidermis. Although the stratum corneum - the outermost layer of the epidermis - is a key contributor to the COF of skin[6], surface damage is not the primary mechanism for blister formation. Rather, blisters occur when cells in the stratum spinosum undergo necrosis due to shear loading[2].

Friction blister studies are supplemented by research seeking to quantify COF properties of skin in general[13, 16]. In these studies, the intrinsic properties of skin itself are considered, often for the purpose of improving ergonomics or cosmetics. However, since COF is also known to be influential to blister formation, they may be drawn upon for blistering applications. Because COF is one of the most studied engineering properties of human skin, blister prevention techniques largely focus on reducing COF or the causes of high COF, such as moisture[17]. COF tends to increase with increasing skin hydration up to a certain point, after which the system transitions to stick-slip behavior[4]. Knapik et. al. applied this concept to blister prevention by showing that antiperspirant application significantly reduced blistering in soldiers[9].

Another key avenue that has been examined is the use of various textiles to mitigate the onset of friction blisters. Knapik et al examined different material combinations of sock materials in the boots of soldiers to reduce blistering[18]. Derler et. al. characterized textile-skin and textile-skin equivalent behavior in terms of COF and normal load[12]. Gerhardt et. al. demonstrated the effect of epidermal hydration on the COF value of skin-textile interfaces[19].

The skin-textile interface is, then, a clear focal point in blister studies. The authors developed the Synthetic Skin Simulant Platform (3SP) to repeatably model human skin in friction blistering applications. The development and demonstration of this construct is documented in a prior manuscript that is currently under review. This system was created in response to the limitations of prior *in vivo* and FEA modeling methodologies. The 3SP has been demonstrated to model the onset and formation of friction blisters using a steel ball probe in prior experimentation conducted by the authors. However, to be a more useful research tool, the 3SP should be able to model fabric-skin interactions just as well as steel-skin interactions. An investigation of two common textile fabrics and two surface treatments has demonstrated which materials and surface treatments are most influential to blister prevention.

Materials and Methods

Platform Design and Preparation

The design of the Synthetic Skin Simulant Platform (3SP) focused on the blistering mechanism of human skin. Blisters form between layers in the epidermis when subjected to shear loading, thus attention was paid to proper selection of materials in light of the reported mechanical properties of real skin. The 3SP implemented a tri-layer design to simulate blister formation under applied shear loading. An illustration of the 3SP structure is shown in Figure 3.

The top layer of the 3SP is referred to as the Epidermal Simulant Layer (ESL). It consisted of 0.80-mm thick transparent silicone rubber, to simulate the stratum corneum. As with human skin, the critical property of this layer is its coefficient of friction (COF). Silicone was chosen because it has been shown to approximate the COF of human skin against a number of surfaces [12]. The transparency of the ESL was also deemed important in order for blister area to be measured after testing, as described below. For each platform constructed, the silicone was cut into a 2.54 x 7.6-cm rectangle to prepare for bonding to the layer below. The Dermal Simulant Layer (DSL) consisted of a 3.18-

mm thick layer of either polyurethane elastomer (McMaster-Carr) also cut into a 2.54 x 7.6-cm rectangle. Prior experimentation by the authors demonstrated that polyurethane was an excellent material to model high-risk anatomical sites of blister formation. Due to the thinness and compliance of the top two layers, the authors found that the ESL and DSL experienced significant substrate effects when they were adhered directly to the mounting substrate, thus the Subdermal Simulant Layer (SSL) was incorporated. The SSL consisted of 318-mm thick neoprene rubber (McMaster) cut to a 7.6-cm square. Another objective of incorporating the SSL into the platform was to simulate the tendons, fat and muscles that sit between bone and the dermis in the body.

A methyl ethyl ketone adhesive (Loctite® No. 79051333) was used to adhere the ESL to the DSL. The ESL and DSL were bonded using the adhesive in thinned (50% acetone dilution, by weight) form to provide smooth, even distribution on the DSL-ESL interface. The adhesive was applied evenly to the surface of the ESL using a paint brush. Any bubbles between the ESL and DSL were manually smoothed out by hand, paying special attention to minimizing the deformation of the layers during application. A flat plate was pressed against the top of the ESL immediately after establishing contact with the DSL to produced smooth bonding across the interface. A distributed compressive load of approximately 55 N was applied for 30 minutes during adhesive curing. A silicone-based adhesive was used to join the DSL to the Subdermal Simulant Layer (SSL), as well as the SSL to the mounting substrate. This latter adhesive had much higher bond strength than the ESL-DSL interface to ensure blistering would occur at the appropriate interface. Adhesive was applied to the top of the SSL layer and the ESL-

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Prior to experimentation, the authors conducted several preliminary tests to optimize the materials and adhesives used in 3SP samples. Since the 3SP goal represented an unexplored field, it was important to find some functional basis from which to begin tests. Prior skin-simulant studies in haptics and cosmetics were helpful to frame the material perspective. To begin finding the best combination of materials and adhesives, the authors selected 10 different elastomer materials based on their durometer stiffness ratings and four different adhesives based upon availability and suggested use. The stiffnesses were qualitatively rated from 'ultra soft' to 'firm' (McMaster), and loosely guided by the work of Derler et al[12].

The most obvious configuration change between the first generation 3SP samples and the current version was the SSL used. A 12.7 mm thick silicone foam was the first material used in this application. It was abandoned in favor of 3.18 mm thick latex rubber due to its deformation under normal loading being higher than was desired. Additionally, handling and cutting the foam was clumsier than with latex. The silicone foam may be useful for modeling structural soft spots on the human body such as the abdomen; however, this region is not typically associated with blistering. Due to the initial decision to use materials with similar stiffness ratings, the evolution of the DSL material was not an area of emphasis during the early stages of development. It was only after experimentation that the effect of the DSL materials was understood. Two ESL materials were tested: a very thin (0.127 mm) silicone film and a thicker (0.8 mm) silicone rubber. The thicker rubber was selected because the thin film was easily torn apart by the testing apparatus.

A primary focal point of the early development of the 3SP was to find which adhesives were useful to the testing procedure. The goal in selecting the best adhesive was to find one that was strong but easily diluted by a solvent. Four different adhesives were tested at the critical interface between the ESL and the DSL. After testing each adhesive, two emerged as the best performers for application: an aerosol-delivered vinyl/plastic adhesive and a tube-delivered ketone based adhesive. Blister performance was very close with each, but the tube delivered system proved to be much better suited for controlled and repeatable dilution and deposition. Two adhesives were tested for the DSL-SSL and SSL-substrate interfaces: superglue and a silicone based adhesive. It was found that the superglue did not bond well with the latex SSL; since the silicone adhesive performed adequately, it remained throughout the entire test process.

Testing Procedure

Testing of the 3SP platforms was accomplished using a custom-built tribometer. This instrument facilitated precise contact between a curved textile mounting plate and a 3SP sample. The mounting plate is a 2.6 x 8 cm piece of aluminum with a radius of curvature of 15 cm, created to securely house textile fabrics. The plate was padded with neoprene rubber, over which various textile fabrics were set and secured. The plate assembly facilitated easy interchange of fabrics to allow for several textiles to be tested.

The two tested fabrics were cotton and denim, each affixed to the mounting bracket in 2.6 x 26-cm strips. The bracket was reciprocated linearly 20 mm across the 3SP sample for 500 cycles at a static load of 25N. The initial point of contact between 3SP samples and the textile plate was approximately 3 cm from one edge of the sample. This end is called the near end. One cycle was a 2-stroke motion. In the first stroke, the plate extended 20 mm toward the end opposite end of the sample at 60 mm/s; this opposite end is called the far end. In the second stroke, the plate receded back to its initial position.

To investigate the effects of friction-reducing coatings, surface treatments of a C18-36/capric/caprylic triglyceride-based skin lubricant (BodyGlide®) and corn starch were deposited onto the ESL immediately preceding testing. Corn starch was dusted onto the surface of the 3SP by hand. The skin lubricant was directly applied from its bar onto the ESL until it was covered. This layer was measured to be approximately 40 μm thick.

Two response variables were identified for the tested 3SP samples: blister area and surface damage. Blister area was determined by using image analysis software (ImageJ) to detect the debonded (blistered) area of a tested 3SP sample. A grayscale threshold technique was implemented in the software to automatically detect the blister boundaries through the transparent silicone ESL layer. Surface damage, being very difficult to objectively measure, was instead characterized on a 1 through 4 ordinal scale; this scale is detailed in Table 6. These two measures, blister area and surface damage, allowed the investigators to determine damage both to the substrate and the surface. A

Scanning Electron Microscope (SEM) was used to obtain images of 25 and 100 X magnification. These images were qualitatively examined to find trends in fabric damage and any deposits from the surface treatments.

Results and Discussion

The data revealed similar patterns in all 3SP samples that formed blisters. The textile mounting plate pushed a noticeable leading edge of ESL material ahead of it during the initial motion of the cycle. This leading edge was very similar to a phenomenon termed the "bow wave" effect in *in vivo* studies conducted by Kwiatkowska et al[14]. As it receded, the material stretched behind it. Blister formation always began at the far end of travel of the textile mounting plate. As the plate reciprocated, the blister would alternately compress into the bow wave as the plate extended and stretch as the plate receded. In some cases, the furthest edge of the bow wave became imprinted on the ESL.

The tested samples were examined using the same regimen and criteria as that of prior research by the authors, capturing data relating to both blister size and surface damage. An example of the final state of a tested 3SP sample is shown in Figure 4. Mean and median results for the blister size and surface damage, respectively, are presented in Table 7.

An analysis of variance (ANOVA) was performed on the blister area to ascertain whether the treatments and fabrics were significant to blister formation. This analysis showed that material type is on the verge of statistical significance ($p=0.058$) with denim causing larger blisters. It was also determined that the surface treatments of skin lubricant and corn starch are significant in blister prevention ($p<0.001$). No interaction between material and surface treatment was observed. Textile material was found to be unimportant ($p=0.747$) to surface damage, but surface treatments were again significant ($p=0.003$). As with blister size, no interaction between surface treatment and material was observed.

These results corroborated qualitative observation of the tests. Corn starch and skin lubricant both mitigated blistering significantly compared to untreated 3SP samples. The authors expected this behavior with skin lubricant due to its advertised use as a consumer product for runners and cyclists. Prior research conducted by the authors has also demonstrated the effectiveness of corn starch at reducing COF values. In repeated uses of fabrics, skin lubricant demonstrated greater blister mitigation. Corn Starch showed diminishing returns when the fabric was used more than twice. In the later stages of its use, blister formation began to occur as with untreated samples. However, in these cases the blistering and surface damage were still mitigated. Skin lubricant was effective through all tests, even using the same fabric swatch. This may be due to the manner in which these treatments decrease COF. In the case of corn starch, the small particulate spheres act as tiny ball bearings between surfaces. The fabrics tended to trap the corn starch over the course of the cycling. Once the particles of corn starch become imbedded in the fabric, it is likely that their performance would degrade. Skin lubricant, on the other hand, appeared to coat the fabric with a thin waxy layer that presumably lubricated the wear interface. Absorption into the fabric, then, decreases the COF of the swatch. COF data for each combination of fabric and surface treatment is presented in Table 8.

During the course of a test, the surface treatment was removed by either being pushed aside or absorbed into the fabric. Skin lubricant-contacting fabrics did not visibly "saturate", while corn starch contacting textiles did. However, subsequent scanning electron microscope (SEM) imaging showed that both treatments were embedded into the fabrics. The visibility of saturation in the corn starch contacting fabrics was greatly aided by the color contrast between textiles and the white corn starch. Cotton fabric showed significant macroscopic deformation and stretching at the interface contact point, while denim showed much less visible effect from treatments and wear. The effect of testing on the cotton and denim samples can be seen at a microscopic level in Figure 5 and Figure 6. Cotton and denim images exhibited very similar trends. The fibers of both fabrics were mildly damaged as compared with untested samples of the same fabrics.

The significance of textile material merits future examination. The trends exhibited by the collected blister size mean values and qualitative observation of the tests suggest that the fabric is a significant variable. Within every subset of surface treatment, blister size was always smaller for cotton fabric samples than those in contact with denim. Qualitatively, this is supported by these fabrics' use in the consumer market. Denim is confined to casual clothing, while cotton is a common material used in athletics. It may be useful to quantitatively validate this trend to help promote innovative new fabrics for blister applications.

Cotton fabric samples were cut to be rubbed against their pattern, so macroscopic deformation was to be expected. Since microscopic damage did not occur in any of the samples, fabrics were demonstrated to be safe for reuse even if they show visible signs of fatigue. However, in implementing blister prevention regimens, surface treatment saturation may be a necessary concern. Tests using corn starch began experiencing diminishing returns after two or three uses in both fabrics. Skin lubricant tests did not demonstrate any reduced effectiveness throughout its testing. Despite this maintained effectiveness, it would behoove users of any surface treatment to favor fresh application and materials over reapplication and reuse.

Conclusions

The authors have tested a newly developed construct called the Synthetic Skin Simulant Platform (3SP) to observe the effect of textiles and surface treatments on blister formation on human skin. The following conclusions are based on the results of this investigation.

- Triglyceride based skin lubricant demonstrated the greatest potential for repeat or heavy use on the body
- Corn starch treatments may be effective in short term, one-time applications as a fast, cheap solution. However, in extended use fabric saturation should be monitored
- While denim is a very robust and strong fabric, it appears to be sub-optimal in applications that may induce blistering

- 3SP behavior is consistent with what one would expect from *in vivo* skin tissue, lending credibility to its use in subsequent blister research

CHAPTER IV

GENERAL CONCLUSIONS

Friction blisters are one of the most common forms of skin damage. Therefore, discovering techniques and treatments to mitigate blister formation will significantly improve the comfort and quality of life among a very broad range of people, from military personnel to those who suffer from skin disorders such as epidermal bullosa (EB). Studies on friction blisters may be significantly bolstered by the repeatable, readily available nature of the Synthetic Skin Simulant Platform (3SP).

The 3SP met the authors expectations as a model to predict blister formation in human skin. The characteristics of 3SP "blisters" are qualitatively very similar to those that form on human skin. Investigation of the cellular makeup of human skin will notice that the 3SP is structurally a highly simplified model. However, the mechanism of blister formation is accurate, and the potential of the 3SP is clearly demonstrated by its performance and response to known phenomena in skin tribology.

Blister formation on the 3SP is directly influenced by varying the COF and stiffness of the ESL and DSL, respectively. Because of the modular design, these values may be adjusted independently to simulate any desired anatomical site of the human body. that dermal stiffness is a significant factor in the 3SP may lead to more innovative analysis of blister formation in human skin. Further studies should be conducted to investigate the interaction of shear speed, normal load and bond strength to clearly understand their influence on blistering in the 3SP.

The effects of textile fabrics and surface treatments agree with the current state of the art in consumer products and with what one would expect. COF mitigation leads to lessened susceptibility to blister formation and surface damage. The 3SP predicts that cotton is a better fabric than denim in blister applications and that lubricants help prevent blister formation. These predictions reinforce the credibility of the 3SP as a useful investigatory tool in future applications. The tested values of the initial experimentation was meant to establish the important variables rather that accurately simulate the exact conditions of human skin. Further optimization of the mechanical properties of the 3SP should occur if it is implemented as a mainstay research tool.

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APPENDIX A

Tables

Table 1: Factor level settings for first fractional factorial experiment

Variable	Low Value	High Value
Surface Treatment	Corn starch	Untreated
Dermal Stiffness	40 Shore OO (PUR)	30 Shore A (neoprene)
Bond Strength	Full strength	50% diluted
Normal Load	3 N	9 N
Shear Speed	25 mm/s	50 mm/s

Table 2: Surface damage characterization

Damage Level	Explanation
1	No visible damage to surface
2	Shallow trough along surface of wear path
3	Waves in the trough
4	Bumps in the trough that protrude above the adjacent surface level
5	Extensive ripples with visible markings of damage and/or tearing

Table 3: Factor level settings for the second experiment

Variable	Low Value	High Value
Surface Treatment	Corn starch	Untreated
Dermal Stiffness	40 Shore OO	30 Shore A
Shear Speed	25 mm/s	50 mm/s

Table 4: Blister and surface damage results from the first experiment. 'Low' and 'high' settings for each parameter are indicated by capital and lowercase letters, respectively. A represents surface treatment, B dermal stiffness, C bond strength, D loading, and E shear rate

Test Configuration	**Blister Area (cm^2)**			**Surface Damage**
	$\overline{x}$	S	n	median
1 (abcDE)	1.165	1.249	6	3
2 (Abcde)	2.444	0.729	6	5
3 (aBcdE)	0.000	0.000	6	1
4 (ABcDe)	1.020	1.390	6	3
5 (abCDe)	1.865	0.749	6	5
6 (AbCdE)	1.049	0.617	6	3.5
7 (aBCde)	0.000	0.000	6	1
8 (ABCDE)	0.532	0.660	6	1.5

Table 5: First Fractional Factorial ANOVA results. * indicates effect has statistical significance at 95% confidence

Source	SS	df	MS	F	p-value	
Surf. Treatment	3.048	5	3.048	4.419	0.042	*
Dermal Stiffness	18.534	1	18.534	26.872	< 0.001	*
Bond Strength	1.049	1	1.049	1.521	0.224	
Normal Load	0.888	1	0.888	1.287	0.263	
Shear Speed	5.002	1	5.002	7.252	0.010	*
Error	28.969	42	0.690			
Total (corrected)	57.490	47				

Table 6: Surface damage characterization

Damage Level	Explanation
1	Surface is superficially scuffed and scratched
2	Shallow deformation occurs across contacted region
3	Bubbled surface at contact area, clear separation, light bow wave imprint
4	Heavy crease at bow wave edge permanently imprinted on ESL, separation

Table 7: Blister and surface damage results from experiment. Each fabric-surface treatment is explained by the description next to the configuration number

Test Configuration	**Blister Area (cm^2)**			**Surface Damage**
	$\overline{x}$	S	N	Median
1 (Denim-Untreated)	6.439	1.013	4	2.5
2 (Denim-Corn Starch)	1.013	0.887	3	2
3 (Denim-Body Glide)	0.557	1.113	4	1.5
4 (Cotton-Untreated)	2.984	3.890	4	2.5
5 (Cotton-Corn Starch)	0.441	0.569	4	2
6 (Cotton-Body Glide)	0	0	4	1

Table 8: Mean coefficient of friction (COF) values for each fabric and surface treatment combination

Test Configuration	**Mean COF**
1 (Denim-Untreated)	0.86
2 (Denim-Corn Starch)	0.65
3 (Denim-Body Glide)	0.43
4 (Cotton-Untreated)	0.98
5 (Cotton-Corn Starch)	0.66
6 (Cotton-Body Glide)	0.44

APPENDIX B

Figures

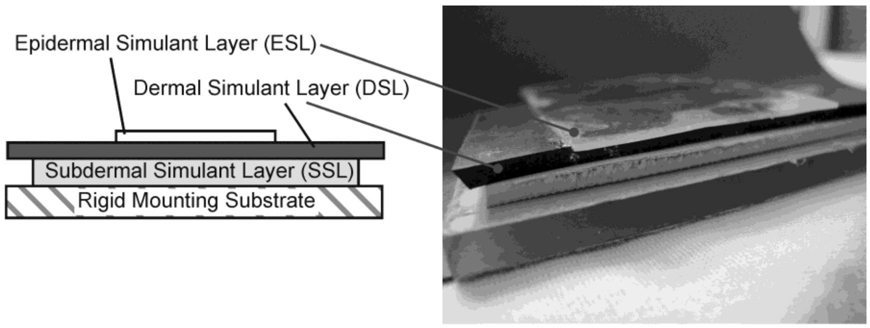

Figure 1: Illustration of the layered structure of the Synthetic Skin Simulant Platform (3SP)

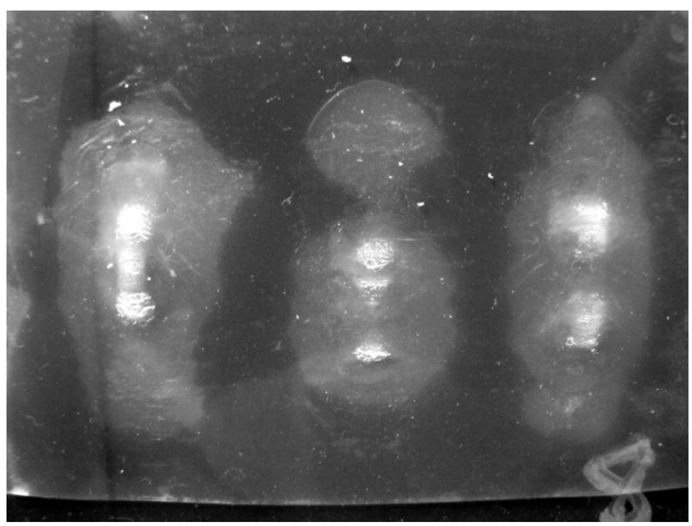

Figure 2: Results of three tests of a 3SP sample under the following conditions: no surface treatment, low dermal stiffness (polyurethane), 50 mm/s shear speed, and 6 N normal load. The light-colored regions are blisters, while the bright white regions indicated significant surface damage

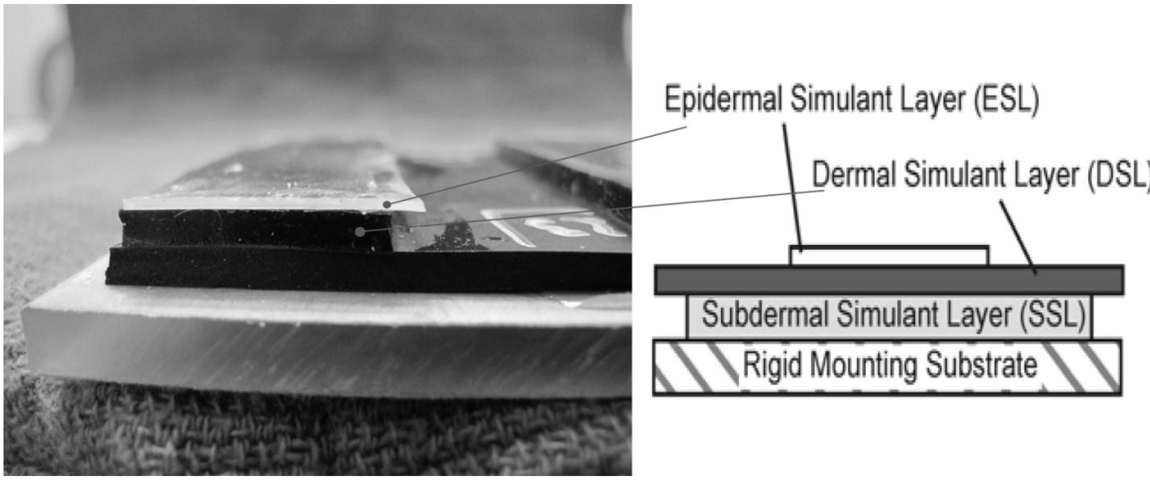

Figure 3: Illustration of the layer arrangement of the Synthetic Skin Simulant Platform (3SP)

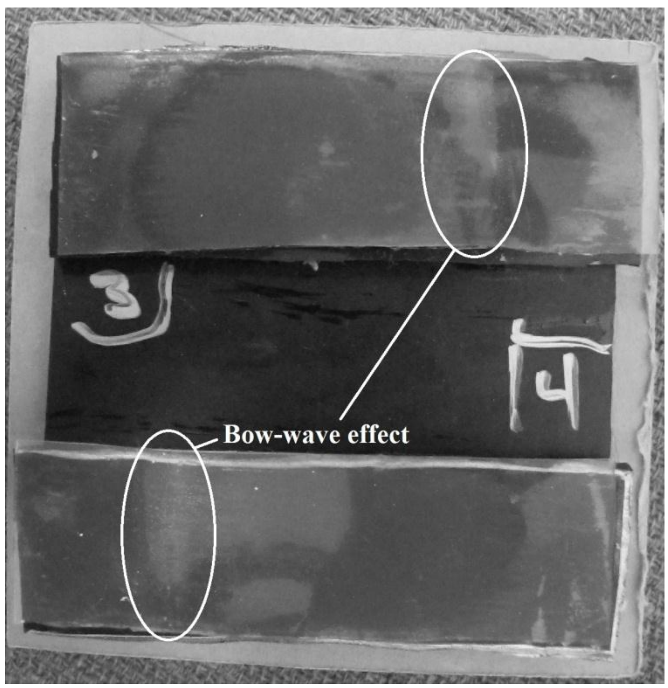

Figure 4: 3SP samples after testing. The lighter regions of the sample represent debonded (blistered) regions of the sample. Bow wave is visible at the blistering point of samples. Surface damage is subtle due to the widespread contact area

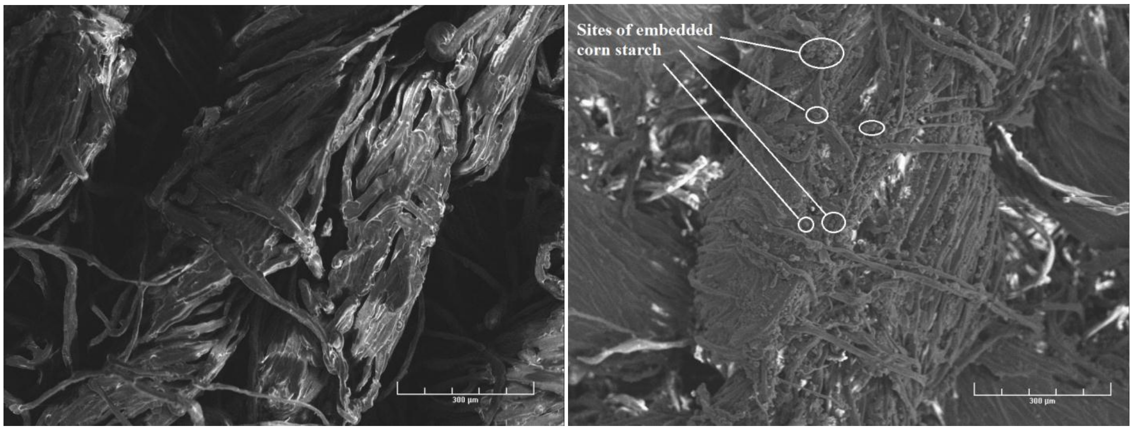

Figure 5: Cotton samples under SEM. (a) was treated with skin lubricant, (b) with corn starch. The (a) fiber filaments exhibit bulbous, waxy strands, while corn starch deposits can be seen in the fibers of (b). Neither samples show signs of significant microscopic damage

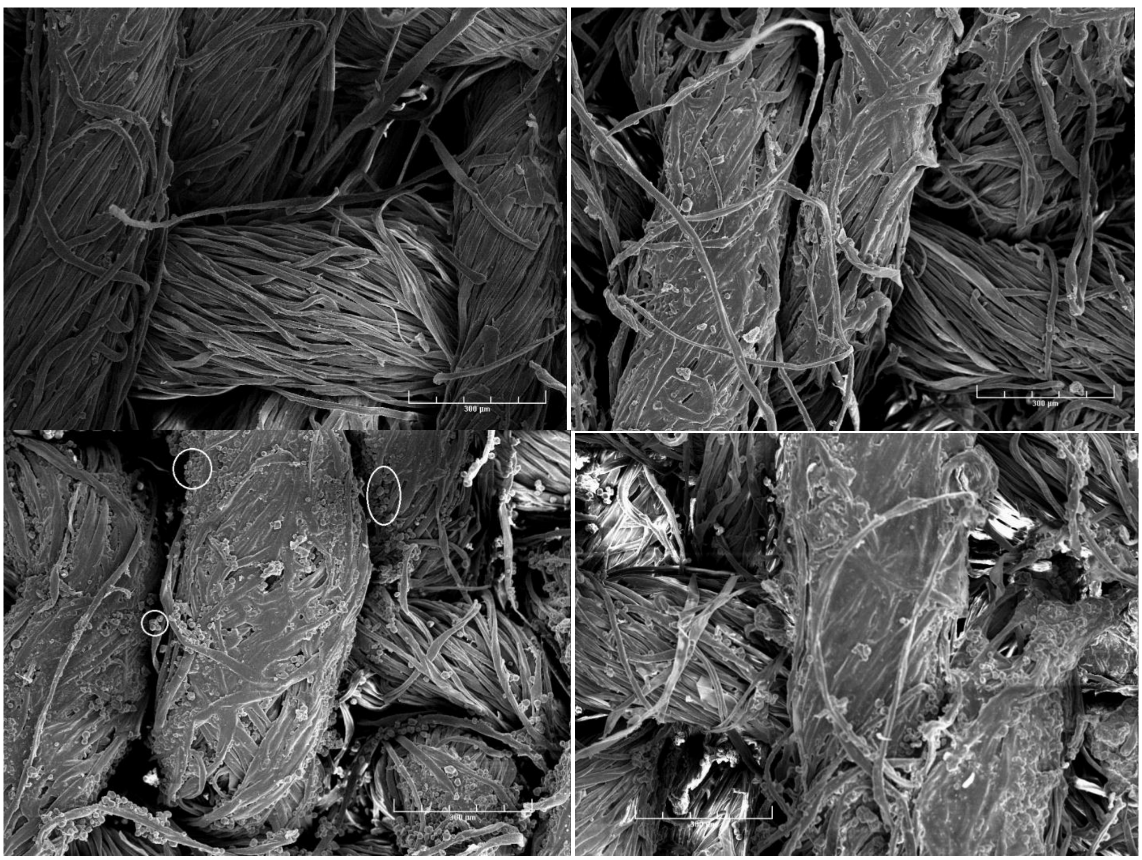

Figure 6: Denim samples under SEM. (a) untested reference, (b) untreated and tested, (c) treated with corn starch and (d) treated with skin lubricant. It can be seen that the fiber weave pattern was disturbed during testing. However, there is little difference in the condition of the filaments in all samples. Those samples that were treated retain residue of each respective surface treatment, with corn starch leaving behind discrete deposits (highlighted regions indicated by circles) and skin lubricant giving a waxy texture

VITA

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